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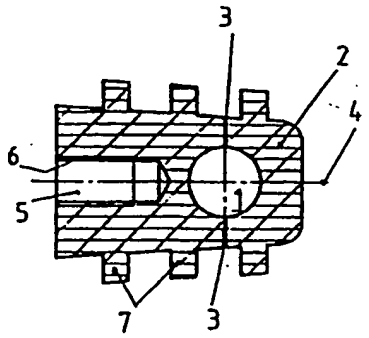
(54) Implantable marker

(57) The implants, consisting of a contrast body (1) and an anchoring body (2), are fixed in stationary fashion in the bone with the aid of a structure of the anchoring body (2), and thereby form within the bone stationary reference points for the measurement of x-ray images.

Fig. 1



P.5854/Wg/IS

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Implantable Marker

The invention pertains to an implantable marker for the establishment of a reference point in human bone tissue.

At various times – at intervals of a year or longer, for example – x-ray images of implanted joint endoprostheses are used to detect shifts such as a sinking or "settling" of the implants into the bone, or shifts of the implant as a result of bone degeneration, as soon as possible. When photographs are taken at different times, different imaging scales of the individual x-ray images and/or different positions of the limbs connected by the replaced joint relative to the photography direction for the various photographs can simulate changes in the position of the prosthesis that are not present. As a result, it is necessary that stationary reference points are present in the bone in each photograph, so that the distances between them and their positions relative to one another can be used to determine changes in the imaging scale and in the position of the bones relative to the photography direction. If – taking into consideration the cited changes in position and scale – the geometrical relationships of these reference points to marking points of the prosthesis are found, then it is possible to determine the previously mentioned "shifts" by the prosthesis, and to capture them quantitatively if necessary.

The task of the invention is to create an implant that can be used to "generate" a stationary reference point in the bone. To perform this task, the invention suggests a contrast body which contrasts with its surroundings in the x-ray image, and the three-dimensional shape of which is configured in such a way that its projection on the film plane makes possible a geometrical determination of the point in space of same for any possible irradiation direction, and an x-ray permeable anchoring body by means of which the contrast body is held stationary within the bone.

The dimensions of the contrast body, which is made, for example, of a metal which generates strong x-ray contrasts – i.e., a metal with the greatest possible density – are kept as small as possible so that the contrast body as a whole can be used as a reference point. Its dimensions are limited downward, first, by the requirement that it still must generate on the x-ray image a perfectly identifiable contrast point; second, the effort involved in its production should of course not become too great.

The most advantageous geometrical form for the contrast body has proven to be a sphere, the diameter of which should be at least 0.2 mm; however, it is also possible to configure it as, for example, a cube or as a round rod or cylinder with rounded or tapered ends. If the dimensions of the contrast body are so large that its image can no longer be considered a "point", then it is additionally possible to specify a point in its image, for example, the center point of a sphere of larger diameter.

In the simplest case, the anchoring body is made of a plastic common in implant technology, e.g., polyethylene; it advantageously exhibits a structure that is suitable for stationary fixing in the bone, which can, for example, consist of ribs, barb-like teeth, blades or threading. In addition, it is useful if the anchoring body exhibits means for the engagement of a setting and/or removal instrument.

Finally, if the contrast body is not resistant to corrosion from bodily fluids, it is advantageous if it is inserted into a liquid-proof housing which serves as the anchoring body.

In the following, the invention will be explained in more detail with the aid of embodiments in combination with the drawing.

Fig. 1 is a longitudinal section I-I from Fig. 2 through a first form of implementation of the implant according to the invention;

Fig. 2 is a view of Fig. 1 from the left;

Fig. 3 partly in section, is a second embodiment, in which

Fig. 4 again represents a view from the left;

Figs. 5 and 6, plan views on a sagittal plane and a frontal plane, show the use of the implants in accordance with the invention in combination with a knee-joint prosthesis, whereby the representation corresponds to the appearance of an x-ray photograph.

In the first embodiment, the contrast body 1 per Figs. 1 and 2 is a metal sphere, for example, a steel sphere, several tenths of a millimeter in diameter. It is embedded in a liquid-proof housing serving as the anchoring body 2; the anchoring body 2, which is made of polyethylene, for

example, is primarily divided along the seam 3 perpendicular to its longitudinal axis 4, whereby hemispherical hollow spaces matched to the dimensions of the contrast body 1 are present in both halves. After the contrast body 1 is inserted, the two parts of the anchoring body 2 are welded together in a liquid-proof manner.

Put into the left face of the anchoring body 2 per Fig. 1 is a bore 5 which is coaxial with the longitudinal axis and which contains threading 6; a setting and/or, if necessary, removal instrument can be fastened in it.

The anchoring body 2 bears on its slightly tapered jacket several collars made up of elastic, tab-like blades 7; these are used to anchor the anchoring body 2 in the wall of bores made in the bone in such a way that it – and thus the contrast body 1 – remains fixed in the bone in stationary fashion for long periods of time.

The contrast body 11 of the second form of implementation (Figs. 3 and 4) consists of a circular cylinder which is provided with ends shaped like conical points 13 and which is placed in an anchoring body 12 configured as a truncated cone with rounded edges, for example, molded into this body made of plastic.

Threading 17 is cut into the conical jacket of the anchoring body 12 as a structure to be fixed in bone. The left face of the anchoring body 12 is provided with a slot 15 into which a screw-in instrument can be inserted.

While the contrast bodies 1 and 11 have dimensions in the tenths of millimeters, for example, the diameter of the anchoring bodies 2 and 12 advantageously amounts to several millimeters, so that manufacturing them and setting them in the bone bores made to hold them do not cause any difficulties.

The knee joint shown in Figs. 5 and 6 is provided with a prosthesis which consists of a femur part 22 that surrounds the condyles of the femur 21 in a cap-like manner, and a tibia part 23. The femur part 22 is produced from metals or a metal alloy used in implant technology, while the tibia part 23, which is anchored in the tibia 25 and fibula 26 by means of pins 24, is made of plastic. Small metal rods that permit identification of the position of the tibia part 23 in an x-ray image are embedded in the plateau of the tibia part 23 or in its pins 24.

Designated by 28 in Fig. 5 is the patella, which is not visible in Fig. 6.

In order to define stationary reference points in the bone, implants 30 in accordance with the invention are set in the femur 21 as well as in the tibia 25 and fibula 26, whereby three elements 30 are arranged in a triangle in the upper leg and in the lower leg. To seat the implants when this is done, it is sometimes possible to use bores that already exist and were used as auxiliary bores during the implantation.

Measurements of the triangle sides and angles make it possible to detect and define changes in the imaging scale and the three-dimensional position of the bones when comparing two x-ray

photographs. Determinations of the distances and angles of the individual implants 30 from marking points 31 in the femur part or, for example, from the small rods 27 in the tibia part, allow – taking into account the differences in scale and position between two photographs – conclusions to be drawn concerning relative movement of the prosthesis parts with respect to the bone.

Patent Claims

1. Implantable marker for the establishment of a reference point in human bone tissue, characterized by a contrast body (1, 11) which contrasts with its surroundings in the x-ray image, and the three-dimensional shape of which is configured in such a way that its projection on the film plane makes possible a geometrical determination of the point in space of same for any possible irradiation direction, and in addition, by an x-ray permeable anchoring body (2, 12) by means of which the contrast body (1, 11) is held stationary within the bone.

2. Implant according to Claim 1, characterized in that the contrast body (1, 11) is a metal sphere.

3. Implant according to Claim 1, characterized in that the contrast body (1, 11) is embedded in fixed fashion in a liquid-proof housing which serves as the anchoring body (2, 12).

4. Implant according to Claim 1, characterized in that the anchoring body (2, 12) exhibits a structure (7, 17) suitable for the stationary fixing in the bone.

5. Implant according to Claim 4, characterized in that the anchoring body (2, 12) exhibits means (5, 6; 15) for the engagement of a setting and/or removal instrument.

Fig. 1

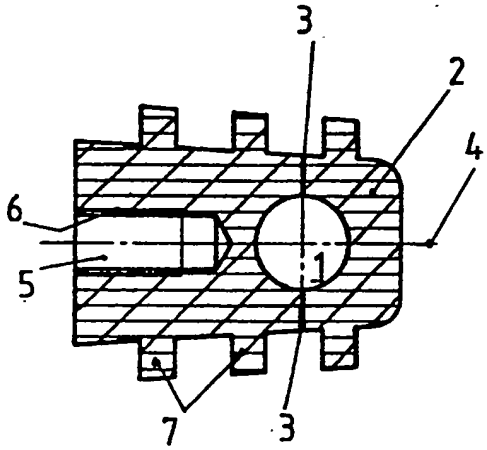


Fig. 2

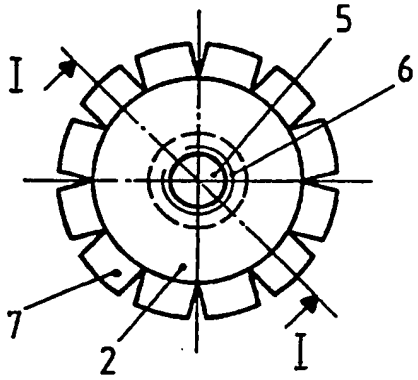


Fig. 3

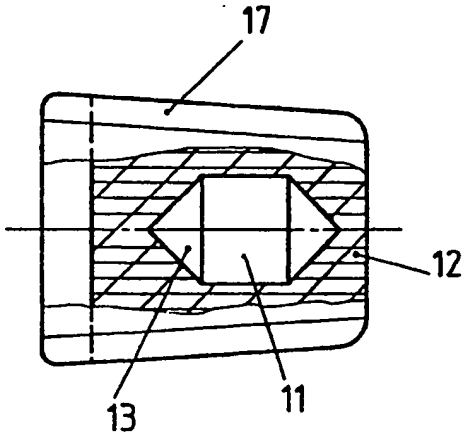


Fig. 4

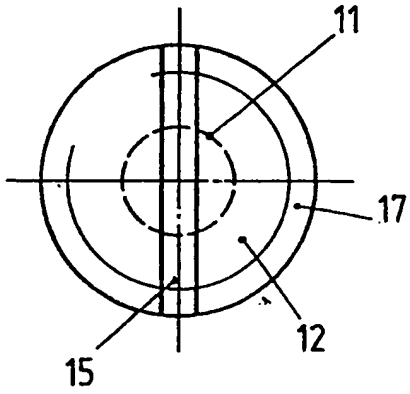


Fig. 5

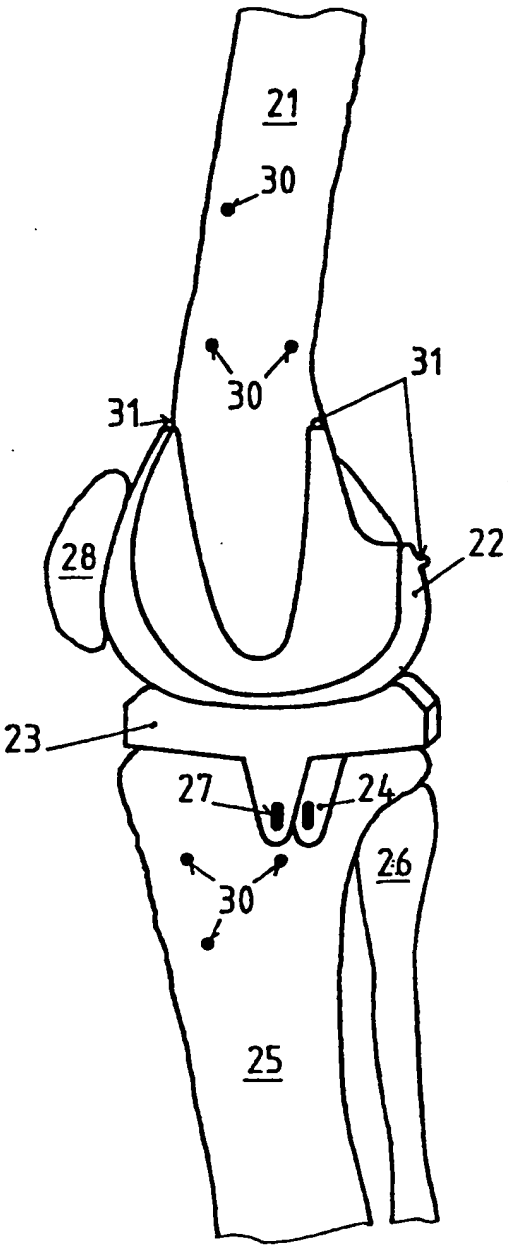
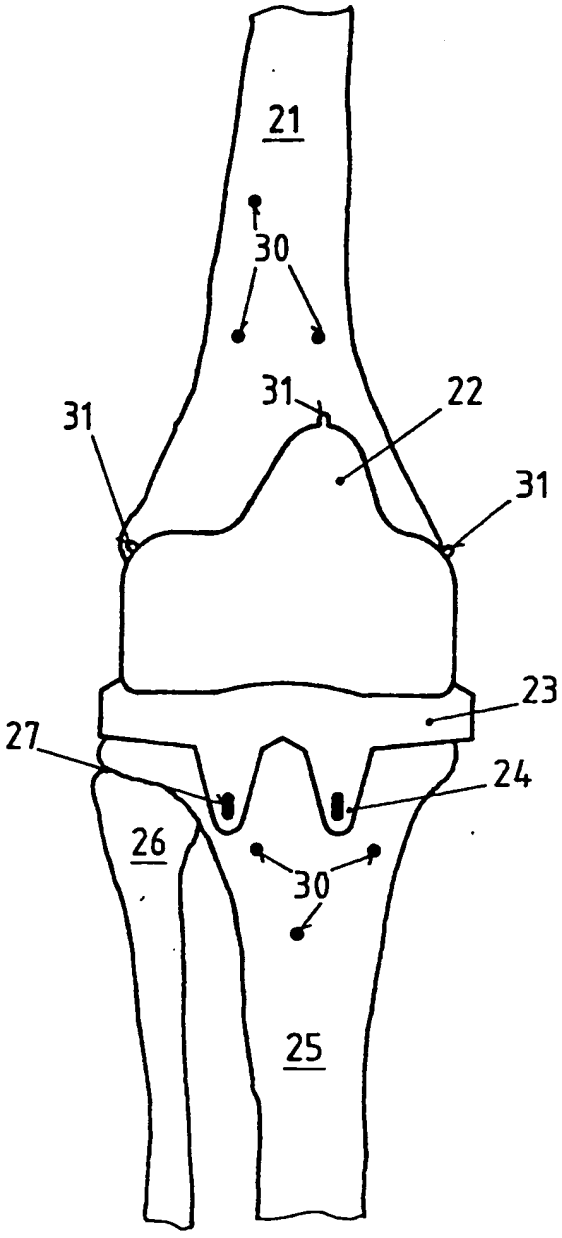


Fig. 6



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Application Number

EP 84 11 1617

European Patent Office

EUROPEAN SEARCH REPORT

PERTINENT DOCUMENTS			
Category	Document reference indicating pertinent parts where necessary	Claims concerned	CLASSIFICATION OF APPLICATION (Int.Cl.⁴)
X	IEEE ENGINEERING IN MEDICINE AND BIOLOGY, Volume 2, No. 1, March 1983, Page 5, New York, US; "System predicts success of implants" * All * ---	1-5	A 61 B 19/00 A 61 B 6/12
A	US-A-4 349 498 (W.H. ELLIS et al.) * All * ---	1-4	
A	DE-A-2 512 983 (P.L. SAMIS) * Page 2, Lines 22-30; Page 3, Line 12 - Page 4, Line 24; Page 9, Lines 1-12 * ---	1-4	
A	US-A-4 373 532 (B.C. HILL et al.) * Column 3, Lines 4-22; Summary * ---	2	Technical Fields searched (Int. Cl.⁴)
A	US-A-4 202 349 (J.W. JONES) * Column 3, Lines 30-57 * ---	3	A 61 B A 61 F A 61 C
A	US-A-3 836 776 (E.H GULLEKSON) ---		
A	US-A-4 277 389 (H.A. SCHEETZ) --- -/-		

The present search report is issued for all claims

Place of search:	Date search completed:	Examiner:
THE HAGUE	2/28/1985	WOLF C.H.S.

CATEGORIES OF DOCUMENTS CITED

X: particularly pertinent by itself;
Y: particularly pertinent in combination with another document in the same category
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T: theory or principles on which invention is based

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D: document cited in application
L: document cited for other reasons

&: member of same patent family, corresponding document

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 84 11 1617

PERTINENT DOCUMENTS			
Category	Document reference indicating pertinent parts where necessary	Claims concerned	CLASSIFICATION OF APPLICATION (Int.Cl.⁴)
A	US-A-4 123 806 (H.C. AMSTUTZ et al.) * Column 6, Lines 12-17; Figures 2, 6 * ---	1,2	
A.	US-A-3 194 239 (C.J.P. SULLIVAN) ---	1,2	
A	ENGINEERING IN MEDICINE, Volume 10, No. 2, April 1981, Pages 97-105, Whitstable, Kent, GB; D. ELAD et al.: "Synthesis of a knee joint endoprosthesis is based on pure rolling" * Page 99, Figure 5 * -----	1,2	
			Technical Fields searched (Int. Cl.⁴)

The present search report is issued for all claims

Place of search:	Date search completed:	Examiner:
THE HAGUE	2/28/1985	WOLF C.H.S.

CATEGORIES OF DOCUMENTS CITED

X: particularly pertinent by itself;
Y: particularly pertinent in combination with another document in the same category
A: general technological background
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P: document appearing in the interim
T: theory or principles on which invention is based

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